DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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JAN - 3 1999

Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004

Docket No.:97A-0247

Dear Mr. Kahan,

This letter is in response to your request, dated June 17, 1997, for an advisory opinion on the preemption of certain New York State tissue bank licensing requirements. You made this request on behalf of Advanced Tissue Sciences, Inc. concerning Dermagraft-TC™, a human fibroblast-derived temporary skin substitute for which FDA approved a premarket approval application (PMA) on March 18, 1997. In addition to your June 17, 1997 request, we have reviewed a letter from the State of New York Department of Health dated September 4, 1997, an additional letter from you dated September 29, 1997, and another letter from the State of New York Department of Health dated October 26, 1999.

Preemption of Device Requirements Under the Federal Food, Drug, and Cosmetic Act

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)) provides that no State or local government may establish or continue in effect any requirement with respect to a medical device that is different from or in addition to any requirement under the act applicable to the device, which relates to the safety or effectiveness of the device or any other requirement applicable to the device under the act. FDA's interpretive regulations concerning section 521 of the act are published in Title 21 of the Code of Federal Regulations Part 808 (21 CFR 808). According to the regulations, as upheld by the United States Supreme Court in Medtronic v. Lohr, 518 U.S. 470 (1996), preemption occurs only when there is a specific state or local requirement applicable to a particular device that is different from or in addition to a specific counterpart requirement that FDA has established for that particular device. 21 C.F.R. 808.1(d).

The New York Requirements

You state that New York's regulation of Dermagraft-TC™ as banked human tissue is preempted because it conflicts with FDA's approval of this product as a device. You also state that certain specific provisions of New York's law are preempted because they are different from, or in addition to, the requirements under the Act.

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1. **New York's designation of Dermagraft-TC™ as "banked human tissue."** New York's designation of Dermagraft-TC™ as "banked human tissue" is not a "requirement with respect to a device" within the meaning of section 521(a) of the act because that designation, by itself, is not a specific requirement for the device. Therefore, FDA has determined that this designation is not preempted by section 521(a) of the act.

2. **N.Y. Pub. Health Law 4364(1) and 4360(1).** These sections require the licensing of a "bank" or "storage facility", which procures, stores, or arranges for the storage of nontransplant organs or tissue for transplantation, therapy, education, research, or fertilization purposes, including autologous procedures. These provisions are general licensing requirements that are not preempted, because they are not specific to the device and, therefore, are not requirements with respect to a device within the meaning of section 521 of the act (21 C.F.R. 808.1(d)(3)). In addition, FDA has not, to date, established any specific counterpart requirements for this device with respect to licensing.

3. **N.Y. Comp. Codes R. & Reg. Title 10, §52-2.** This section sets out certain requirements for tissue banks.

a) **Appointing a tissue bank director.** This requirement is not preempted because it is not specific to the device and, therefore, is not a requirement with respect to a device within the meaning of section 521 of the act. In addition, FDA has not, to date, established any specific counterpart requirements for this device with respect to appointing a tissue bank director.

b) **Recordkeeping.** This requirement is not preempted because it is not specific to the device and, to date, FDA has not established any specific counterpart requirements for this device with respect to recordkeeping.

c) **Donor selection.** This requirement is not preempted because it is not specific to the device and, to date, FDA has not established any specific counterpart requirements for this device with respect to donor selection.

d) **Specimen samples.** This requirement is not preempted because it is not specific to the device and, to date, FDA has not established any specific counterpart requirements for this device with respect to specimen samples.

e) **Instrument maintenance and disposal techniques.** This requirement is not preempted because it is not specific to the device and, to date, FDA has not established any specific counterpart requirements for this device with respect to instrument maintenance and disposal techniques.

f) **Tissue retrieval transport, storage, and handling.** This requirement is not preempted because it is not specific to the device and, to date, FDA has not established any specific counterpart requirements for this device with respect to tissue retrieval transport, storage, and handling.

You also imply that several of the provisions listed above are in conflict with FDA's Quality Systems Regulation (21 CFR Part 820). However, you have not shown, and we have not found, any specific conflict.

4. **N.Y. Public Health Law § 4364(5).** This section provides that fees may be charged only for services provided and costs related to the provision of services. In your request for an advisory opinion, you stated that this section prohibits the sale of tissue for valuable consideration and, therefore, is in conflict with FDA's approval of the device for

commercial distribution. In a letter dated October 26, 1999 (copy enclosed) to Margaret M. Dotzel of the Food and Drug Administration, Jeanne V. Linden, M.D., M.P.H., Director, Blood and Tissue Resources, State of New York, Department of Health stated: "4364(5) is not being interpreted as prohibiting a fee for services rendered at a profit." In accordance with the regulations governing preemption under section 521, FDA takes administrative interpretations into account in determining whether a particular State or local requirement is preempted (21 CFR 808.20 (c)(1)). In light of this interpretation by the State of New York, FDA has determined that this provision is not different from or in addition to any FDA requirement and, therefore, is not preempted by section 521 of the act.

If you have any questions about this opinion, please contact Joseph M. Sheehan of our Center for Devices and Radiological Health at (301) 827-2974.

Sincerely yours,

Margaret M. Dotzel
Acting Associate Commissioner
for Policy

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

October 26, 1999

Margaret M. Dotzel
Food and Drug Administration
Mail Code HF-13
5600 Fishers Lane
Rockville, MD 20857-1706
By Fax: 301-594-6777

Dear Ms. Dotzel:

The New York State Department of Health's Blood and Tissue Resources Program is charged with regulatory oversight of tissue banks and nontransplant anatomic banks. The New York Sate statutory provision prohibiting the sale or transfer of tissue for valuable consideration (Public Health Law §4364(5)) is not being interpreted as prohibiting a tissue bank from charging a fee for services rendered at a profit. Many for-profit entities are licensed to operate in New York. Examples include skin banks such as Genzyme Tissue Repair, Collagenesis, Organogenesis, Ortec International, Advanced Tissue Sciences, Lifecell Corporation; cardiovascular tissue banks, such as CryoLife, Inc; musculoskeletal tissue banks, such as Osteotech and Regeneration Technologies; and numerous reproductive tissue banks and umbilical cord blood banks.

Please let me know if you require further information. Thank you.

Sincerely,

Jeanne V. Linden, M.D., M.P.H.
Director, Blood and Tissue
Resources

cc: Judy L. Doesschate, Esq.

Routing and Transmittal Slip DATE: December 30, 1999

TO:

Bill Hubbard
Joseph Sheehan
Beverly Rothstein
Linda Kahan

	Action		File		Note & Return
	Approval		For Clearance		Conversation
	As Requested		For Correction		Prepare Reply
	Circulate	x	For Your Info.		See Mee
	Comment		Investigate		Signature
	Coordinate		Justify		

Remarks:

The attached letter to Jonathan Kahan, Hogan & Hartson is a response to his request for an advisory opinion on the preemption of NY State tissue bank licensing requirements, made on behalf of Advanced Tissue Sciences, Inc.

Peggy Dotzel phone (301) 827-3360
fax (301) 594-6777